



UNITED STATES PATENT AND TRADEMARK OFFICE

ca
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/542,162 | 07/12/2005 | Bart De Spiegeleer | PRD2018USPCT | 8260 |

27777 7590 11/16/2007
PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

| |
|----------|
| EXAMINER |
|----------|

JAVANMARD, SAHAR

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1617

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

11/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/542,162 | Applicant(s) DE SPIEGELEER ET AL. | |
| | Examiner SAHAR JAVANMARD | Art Unit 4133 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12 July 2005</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|--|--|

DETAILED ACTION

The Office Action is in response to the 371 of PCT/EP04/00147 filed July 12, 2005. Amended claims 1-10 are being examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granstrom et al. (WO 98/43644) in view of Melhorn et al. (US Patent No. 4826842).

Granstrom teaches formulations useful for the treatment of Equine Protozoal Myeloencephalitis (EPM) in a horse comprising a triazine-based anticoccidial. Both triazinedione and triazinetrione compounds, namely diclazuril among others compounds are taught (page 6, lines 1-4).

Granstrom further teaches the formulations can additionally include lubricating agents, wetting agents, emulsifying and suspending agents, preserving agents, sweetening agents or flavoring agents (page 9, 13-20).

Granstrom does not teach a base system nor does the reference specifically teach examples of each type of agent (i.e., emulsifier, etc...).

Mehlhorn teaches triazinetrione agents and formulations for combating parasitic protozoa in fish. The formulation consists of the active ingredient in 1 ppm to 10% by weight. Further, Mehlhorn teaches the preparation of solutions consist of dissolving the active compound in a polar water-soluble solvent which either gives an alkaline reaction or to which an alkaline water soluble substance is added wherein the pH of the solution is 8-10 (column 4, line 62-column 5, line 2). The bases that are taught in the instant reference in order to establish alkalinity of the solution include basic amino acids, bases based on ethylenediamine, inorganic bases such as sodium carbonate.

Mehlhorn teaches the possible water-soluble solvents for such formulations to include ethyl alcohol, isopropyl alcohol, benzyl alcohol, glycerol, propylene glycol, polyethylene glycols, poly(oxoethylene)-poly(oxypropylene) polymers, basic alcohols, such as mono-, di- and triethanolamine, ketones, such as acetone or methyl ethyl ketone, esters, such as ethyl lactate, and furthermore N-methylpyrrolidone, dimethylacetamide and dimethylformamide, and furthermore dispersing and emulsifying agents, such as polyoxyethylated castor oil, polyethylene glycol sorbitan monooleate, polyethylene glycol stearate, or polyethylene glycol ethers and polyethylene glycol alkylamines (column 5, lines 10-21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the triazinedione/trione formulations taught by Granstrom to treat EPM and have incorporated a base system into the triazinetrione formulations as taught by Mehlhorn. The motivation is that there is a constant strife toward improving formulations to enhance the methods of administration for treatment of the vast array of diseases to the subjects in need thereof.

Furthermore, the alcohols and emulsifying agents taught by Mehlhorn are well known to one of ordinary skill in the art. The type and amount of each component of the compositions are deemed to be manipulatable parameters practiced by a person skilled in the art to obtain the best possible formulations.

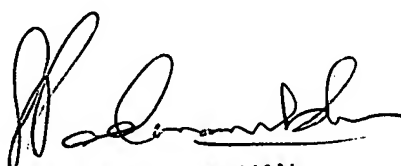
Conclusion

Claims 1-10 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY STUCKER can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER